

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mahler et al.

Art Unit: To Be Assigned

Appl. No: To Be Assigned

Examiner: To Be Assigned

Filed: Herewith

Atty. Docket: 0273-0007

For: **Allergy Vaccines**

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application, Applicants herewith respectfully request the following amendments:

***In the Claims:***

Please cancel claims 1-11 without prejudice to or disclaimer of the subject matter therein.

Please add the following new claims:

12. (new) A method for treating or preventing an allergic disorder, comprising administering from two to six times to a patient in need thereof a composition comprising a derivative of an allergenic protein having a reduced allergenic activity compared with the allergenic protein from which it is derived, wherein the time intervals between administrations are at least 14 days.

13. (new) The method of claim 12, wherein the composition induces blocking antibodies.

14. (new) The method of claim 12, wherein the composition is administered to the patient from three to five times.

15. (new) The method of claim 14, wherein the composition is administered to the patient four times.

16. (new) The method of claim 15, wherein the time interval between the third and the fourth administration being longer than the time intervals between the first three administrations.

17. (new) The method of claim 12, wherein, during each administration, substantially the same dose of the derivative is administered.

18. (new) The method of claim 17, wherein, during each administration, a dose of at least 5  $\mu\text{g}$  of the derivative is administered.

19. (new) The method of claim 18, wherein, during each administration, a dose of at least 100  $\mu\text{g}$  of the derivative is administered.

20. (new) The method of claim 12, wherein the allergenic protein is Bet v 1.

21. (new) The method of claim 12, wherein the allergenic protein is selected from the group consisting of: major grass pollen allergens, mite allergens, bee venom allergens and animal hair dander allergens.

22. (new) The method of claim 12, wherein the composition further comprises an adjuvant.


23. (new) The method of claim 12, wherein the allergenic activity of the derivative is less than 50% of the allergenic activity of the allergenic protein from which it is derived.

### REMARKS

Claims 12-23 are pending in the current application. Claims 1-11 have been canceled and claims 12-23 have been added to conform canceled claims 1-11 to domestic practice. Support for claims 12-23 is found in, *inter alia*, original claims 1-11. This amendment is believed to introduce no new matter, and thus, its entry is respectfully requested.

Applicants believe that the present application is in condition for examination. If for any reason, the Examiner believes that personal communication will expedite prosecution of this application, then the Examiner is invited to contact the undersigned at the phone number provided.

Respectfully submitted,  
SHANKS & HERBERT

By:   
Toni-Junell Herbert  
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Date: 12/27/01

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